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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,585

10/18/2003

Deanna Jean Nelson

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04/25/2006

Deanna J. Nelson, Ph.D.
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Cary, NC 27513

EXAMINER

WHITE, EVERETT NMN

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/688,585	Applicant(s) NELSON, DEANNA JEAN	
	Examiner Everett White	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 10 is/are allowed.
- 6) ☒ Claim(s) 1-7,9 and 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed January 11, 2006 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) New Claims 19 and 20 have been added;
 - (B) Claims 1-6, 9, 10 and 12-17 have been amended;
 - (C) Comments regarding Office Action have been provided drawn to:
 - (I) claims objection, which have been withdrawn;
 - (II) 112, 2nd paragraph rejection, which have been withdrawn;
 - (III) 102(b) rejection, which has been maintained for the reasons of record;
2. Claims 1-20 are pending in the case.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Duplicate Claims

4. Applicant is advised that should Claim 16 be found allowable, Claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, First Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 1-7, 9, 12-14, 16 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. Claims 1-7, 9, 13, 16 and 19 were amended to recite that "R is a sugar, with the exception that the sugar is not D-glucose". However, the instant specification does disclose that "R may be a 1-deoxy-D-glucosyl" on page 10, line 22, which suggests that the language "the sugar is not D-glucose" disclosed in said claims is not supported in the instant specification. Hence, this unsupported language in the claims set forth "new matter" which is not proper under 35 U.S.C. 112, first paragraph.

Claims 12-14 were broadened by changing the passage "pharmacologically active moiety having a molecular weight that is less than about 1000 Daltons" to recite "drug or therapeutic agent" which reads on compounds not supported in the instant specification. This unsupported claim language set forth "new matter" which is improper under 35 U.S.C. 112, first paragraph.

7. Applicant's arguments with respect to Claims 1-7, 9, 12-14, 16 and 19 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112, Second Paragraph

8. Claims 11, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11, line 7, recites a process step that involves alkylating the amino group of 5-aminosalicylic acid with a poly(ethylene glycol) chain having an aldehyde or halide substituent on at least one terminus. However, the term "alkylating" refers to the substitution of an alkyl group for a hydrogen atom in a cyclic compound. There is no indication in the instantly claimed procedure that an alkyl group is being substituted since the reactants are a poly(ethylene glycol) and an amino group.

In Claim 14, line 5, the phrase "general formula (I)" lacks clear antecedent basis since a "formula (I)" has not been disclosed in the claim.

Claim 15 is incomplete because the preamble of the claim is drawn to a method of prophylactically or interventionally delivering 5-aminosalicylic acid to the gastrointestinal tract, but the body of the claim only discloses a description of the 5-amino-

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salicylic acid derivative composition and does not set forth a specific type of delivery process as proffered in the preamble of the claim. Hence Claim 15 is a substantial duplicate of Claim 14, which is drawn to a method of prophylactically or interventionally treating an inflammatory disease in the gastrointestinal tract of a human or non-human mammalian subject, since no delivering procedure is disclosed.

9. Applicant's arguments with respect to Claims 11, 14 and 15 have been considered but are moot in view of the new ground(s) of rejection.

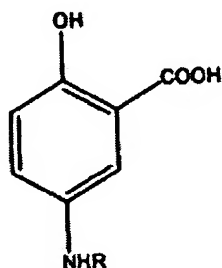
Claim Rejections - 35 USC § 102

10. Claims 1-3, 5, 6, 13 and 16-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Tjoernelund et al (*Journal of Chromatography*, "Stability of 5-Amino-salicylic Acid and its Metabolites in Plasma at -20°C: Formation of N-β-D-Glucopyranosyl-5-Aminosalicylic Acid", 1991, Vol. 570, No. 1, pp. 224-228) for the reasons disclosed on pages 3 and 4 of the Office Action mailed September 13, 2005.

11. Applicant's arguments filed January 11, 2006 have been fully considered but they are not persuasive. The negative limitation amended in the claims wherein "R is a sugar, with the exception that the sugar is not D-glucose" has not been considered in the claims since this limitation has been classified as new matter. See the above rejection under 35 U.S.C. 112, first paragraph. Applicant argued against the rejection of the claims on the ground that the N-β-D-glucopyranosyl-5-aminosalicylic acid (Glc-5-ASA) composition disclosed in the Tjoernelund et al reference is not stable. This argument is not persuasive since the Tjoernelund et al reference discloses on page 226, 4th paragraph, that no decrease in the concentration of Glc-5-ASA was observed in plasma spiked with Glc 5-ASA and stored at -20°C for eight months, which suggests a stable Glc-5-ASA. The additional arguments presented by Applicant regarding additional properties and various use of the 5-aminosalicylic acid derivative composition of the instant claims have been noted, but are not persuasive since a difference in intended use cannot render a claimed composition novel. Note *In re Tuominen*, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F.2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161.

Allowable Subject Matter

12. Claims 8 and 10 are allowed.
13. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach or fairly suggest a therapeutic 5-aminosalicylic acid derivative composition having the general formula.



wherein R is a poly(ethylene glycol) chain-containing residue having the general formula $-\text{CH}_2\text{CH}_2\text{CH}_2-(\text{CH}_2\text{CH}_2\text{O})_n-\text{R}_1$, wherein R_1 is H or a linear or branched lower alkyl group having from one to about 6 carbons, and n is a positive integer from about 3 to about 20; and the method of preparing a therapeutic 5-aminosalicylic acid derivative composition of Claim 10.

Summary

14. Claims 8 and 10 are allowed; Claims 1-7, 9 and 11-20 are rejected.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

16. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

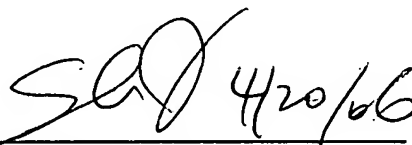
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang, can be reached on (571) 272-0627. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



E. White



Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600